510 (k) Summary

A. Submitter Information:

Submitter's Name:	PROMEPLA SAM
Address:	9 Avenue Prince Albert II "LE COPORI" MC 98000 MONACO (Principality of)
Contact Person:	Mohamed Rekik
Contact Person's Number:	(377) 97984233
Contact Person's Fax:	(377) 92056150
Date of Preparation:	January 23, 2014

B. Device Name:

Trade Name:	Bi-Flex Ureteral Access Sheath
Common Name:	Ureteral Access Sheath
Classification Name(s):	Accessories, Catheter, G-U
Produce Code:	KNY
CFR Reference:	21 CFR 876.5130

C. Predicate Device Name:

Trade Name:	ROCAMED RocaUS Platinum (K120160)

D. Device Description:

The Bi-Flex Ureteral Access Sheath is designed to create a conduit for urological procedural instruments. The device consists of two components: a flexible, coil reinforced sheath and a semi-rigid dual lumen dilator catheter with tapered distal tip. Both components are radiopaque and have hydrophilic coating. This device is sold in two sizes,10/12 and 12/14 FR, and two lengths, 35 and 45 cm.

E. Intended Use:

The Bi-Flex Ureteral Access Sheath is intended to be a conduit for passage of endoscopes and other urological devices for the purpose of performing ureteroscopy procedures. The dual working lumen dilator with luer lock connections allows the user to insert guidewires and fluids.

F. Technological Characteristics Summary:

The Bi-Flex Ureteral Access Sheath is flexible coil reinforced sheath with hydrophilic coating. The device can be inserted by placing the dilator/sheath assembly over a guidewire, inserting it into the patient and unclipping the dilator from the sheath and removing the dilator, leaving the sheath in place. The sheath allows for safe passage of endoscopes, injection or aspiration of fluids and other related instruments.

Table 1 provides a comparison summary of the technological characteristics of the Bi-Flex Ureteral Access Sheath versus the predicate devices.

Table 1

Summary of Equivalence of the Bi-Flex Ureteral Access Sheath to Predicate Device

	Proposed Device	Predicate Device
Product Name **510(k) Number**	Bi-Flex Ureteral Access Sheath	ROCAMED RocaUS Platinum
Product Code, Regulation #, Name	KNY 21 CFR 876.5130, Urological catheter and accessories.	KNY 21 CFR 876.5130, Urological catheter and accessories.
Manufacturer	Promepla SAM	Promepla SAM
Intended Use	The Bi-Flex Ureteral Access Sheath is intended to be a conduit for passage of endoscopes and other urological devices for the purpose of performing ureteroscopy procedures. The dual working lumen dilator with luer lock connections allows the user to insert guidewires and fluids.	The ROCAMED RocaUS Platinum is intended to be a conduit for passage of endoscopes and other urological devices for the purpose of performing ureteroscopy procedures. The dual working lumen dilator with luer lock connections allows the user to insert guidewires and fluids.
Reuse Status	Disposable. For single patient use only	Disposable. For single patient use only
Sterile	Yes	Yes
Lumen	2	2
Dilator Material	LDPE+$BaSO_4$	LDPE+$BaSO_4$
Sheath Material	Pebax-SST-PTFE	Pebax-SST-PTFE
X-Ray Opaque	Yes	Yes
Coil Reinforced	Yes	Yes
Fr Size	10/12,12/14	10/12,12/14
Length	35, 45 cm	35 cm
Guide wire Compatibility	0.032", 0.035"	0.032", 0.035"
Atraumatic Tip	Yes	Yes
Tapered Dilator	Yes	Yes
Radiopaque Marks	Yes	Yes
Hydrophilic Coating	Yes	Yes
Injection of Contrast Media	Yes	Yes
Proximal End Funnel	Yes	Yes

G. Performance Data:

Results of physical and functional testing support a determination of substantial equivalents for the Bi-Flex Ureteral Acces Sheath when compared to the predicate device.
The Bi-Flex Ureteral Access Sheath is substantially equivalent to devices currently market approved in terms of intended use, technology, principles of operation and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 17, 2014

Promepla SAM
Mohamed Rekik
Quality Manager
9 Avenue Albert II, "Le Copori"
MC 98000 MONACO

Re: K140441
Trade/Device Name: Bi-Flex Ureteral Access Sheath
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: KNY
Dated: January 23, 2014
Received: February 21, 2014

Dear Mohamed Rekik,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140441

Device Name
Bi-Flex Ureteral Access Sheath

Indications for Use *(Describe)*

The Bi-Flex Ureteral Access Sheath is intended to be a conduit for passage of endoscopes and other urological devices for the purpose of performing ureteroscopy procedures. The dual working lumen dilator with luer lock connections allows the user to insert guidewires and fluids.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joyce M. Whang -S

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